REMARKS

Applicant hereby cancels claims 1- 28, and adds new claims 29-34. Accordingly, claims 29-34 are currently pending.

Cancelled claims 1 through 28 have been rejected as obvious under 35 U.S.C. § 102(b) as anticipated by either M.W. Blessinger patent No. 4,920,971 issued May 1, 1990 or R.P. Eaton patent No. 5,413,582 issued May 9, 1995. Applicant respectfully submits that new claims 29 and 32 and claims 30, 31, 33 and 34 dependent thereon, are patentably distinct from the teachings of the Blessinger and Eaton references.

In particular, applicant's invention relates to methods and apparatus for facilitating insertion of a needle, e.g., a catheter or the like, into a human vein for fluid administration (administration of plasma, medicines, and/or nutrients as examples) or for blood removal (as for diagnostic testing). Locating veins and inserting one or more needles into a vein can be difficult in many instances (for example, in the case of some elderly, infants and others – especially for health care workers of limited experience).

To this end, applicant's invention employs a pressure cuff (e.g., 10 in Fig. 1) placed about the limb of the patient containing the vein to be used. The cuff is placed on the subject's limb between the heart and the needle insertion point in the vein. The pressure cuff is inflated by a pump 12 via intermediate conduit tubing. At this point, valve 16 lets air flow between the pump and cuff which thus becomes progressively inflated.

A pressure gauge (e.g., 18 in Fig. 5) provides a visual output indication of the then obtaining cuff pressure. During inflation, a progressively increasing pressure level is presented (e.g., a gauge needle deflection progressively away from zero).

The pressure is pumped up to a level higher than the subject's systolic pressure – i.e., above the highest blood pressure in the person any time during a full heart cycle corresponding to the maximum closure of the left heart ventricle. See, e.g., page 6, lines 17-18 ("The occluding band is inflated until the radial pulse is no longer palpable."). With a vein-occluding pressure above systolic pressure, no blood can flow through the vein below the cuff or distally in the limb, i.e., cannot flow in the vein at the needle insertion area, at any point in a heart cycle.

Thereafter, the valve is partially opened to the atmosphere, permitting air to slowly vent outward from the cuff. The progressively lower cuff pressure is indicated at first by an essentially smooth, progressively lowered indicator pressure (e.g., a gauge needle slowly progressing toward lower pressure values).

When the cuff pressure falls below systolic pressure, there are blood pulses in the vein for the limited portion of a composite heart cycle when the left ventricle closure output pressure exceeds the cuff occluding pressure. This is indicated by a pulsing, alternately rising-then-lowering oscillating visual indication on, for example, the pressure gauge. See, e.g., page 6, line 22-page 7, line 1 ("Additionally, a gauge with a needle, which pulses with each cardiac contraction, may be utilized.") The health care professional responds to the indicator oscillations signaling a cuff pressure below systolic by operating the valve to shut down further air escape in the cuff thus suspending further pressure relief in the cuff.

With this sub-systolic pressure preserved, the vein of interest is distended during part of the heart cycle. The medical professional can palpate the vein by repeated finger tapping to readily locate the vein (which may be apparent even without tapping under these conditions), and to insert the needle in a much easier, secure and reliable fashion than without the method and apparatus of the present invention.

This methodology, mode of operation and apparatus, definitively recited in new claims 29-34, is not taught by either of the cited Blessinger or Eaton references. Blessinger employs two cuffs 14 and 16 which are activated seriatim to engorge blood in a vein to be accessed. A first, smaller inflatable cuff 14 is inflated until blood flow stops in a subject's limb, while the second, distally located significantly larger cuff 16 is not inflated. With the vein thus isolated from heart activity by inflated cuff 14, the second cuff 16 is then fully inflated to squeeze blood formerly resident in the vein portion underlying the bladder 16 into the distal vein portion so that the vein becomes fixedly engorged.

Beyond the questionable medicine of pressurized (positive displacement pumping) forced overfeeding a vein, this prior art arrangement bears no relation to the invention of applicant. The device of Blessinger does not rely upon or create any limb occluding pressure below systolic where an indicator indicates pulses corresponding to cardiac contraction of the subject. The notion of such a pressure is not present for any purpose in the reference; and a fortiori a pressure below systolic where an indicator indicates pulses corresponding to cardiac contraction of the subject is not maintained in the apparatus or methodology of Blessinger. Indeed and directly to the contrary, the Blessinger cuffs are either fully pressurized or are unpressurized. The structures are completely different; the methodology is completely different.

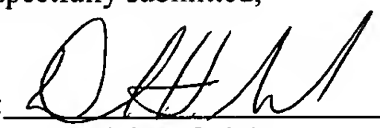
The same is true of the Eaton reference which simply discloses a disposable pressure cuff to serve as a tourniquet to control blood pressure during a medical procedure. There is no disclosure in Eaton at all of occluding and maintaining a limb pressure below systolic where an indicator indicates pulses corresponding to cardiac contraction of the subject. There is no disclosure in Eaton at all about any method or apparatus to facilitate intravenous needle insertion at all.

In view of the foregoing remarks, it is submitted that all pending claims are in condition for allowance. Accordingly, allowance of all pending claims is requested.

The Commissioner is hereby authorized by this paper to charge any fees due in connection with the filing of the response to Deposit Account No. **50-0310**.

Respectfully submitted,

October 2, 2003
Date

By: 

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